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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,966	12/03/2003	Catherine A. Pipenhagen	47563.0012	4374

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/726,966	PIPHENHAGEN ET AL.	
	Examiner	Art Unit	
	Julian W. Woo	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20, 22, 25, 28, 31 and 34-42 is/are rejected.
- 7) ☒ Claim(s) 21, 23, 24, 26, 27, 29, 30, 32, 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-14 and 34-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to base claims 1, 34, 37, and 41 it is not certain how the volume what constitutes a rectangle that is "open." Also, do the "rectangular dimensions" refer to the dimensions of the "shape," to the "open rectangle," or to both?

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3,15,19, 20, 22, 25, and 28 rejected under 35 U.S.C. 102(b) as being anticipated by Rousseau (6,425,924). Rousseau discloses, in figures 1-4, a tissue puncture closure device having a filament (22), an anchor (14) or internal component, a

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sealing plug (another element 14) with a high surface-area-to volume ratio or first external component, where the sealing plug comprises at least two folds or at least two S-folds, where the first external component comprises a filament weave pattern, where the filament weaves through a first portion and second portion or first and second halves of the filament weave pattern, where the filament weaves through the internal component at approximately a middle of the external component, where the first component is folded latitudinally, and where the sealing plug comprises two cross members having a weave pattern.

5. Claims 1, 4, 15-18, 37-39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,662,681). disclose, in figures 1-3, a tissue puncture closure device and a method of sealing an internal tissue puncture with the device, where the device has a filament (34D), an anchor (32) or internal component, a sealing plug (30) with a high surface-area-to volume ratio or first external component, where the sealing plug comprises a collagen sponge and a generally rectangular shape folded latitudinally, where the sponge is folded twice longitudinally (i.e., compressed in a longitudinal direction), where the sponge is substantially S-shaped (if viewed from a side opposing the view of fig. 3), where the sealing plug fills an internal tissue puncture, and where the anchor and sealing plug (or closure device) are inserted into an insertion sheath (100 or 104).

6. Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Nash et al. (5,312,435). Nash et al. disclose, in figure 5 and in col. 3, line 45 to col. 4, line 64, a tissue puncture sealing device with an internal component (32) or stiff anchor,

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a first external component (28) that is a collagen sponge, and a filament (30), where the sponge is compressed and deformed or impinged by the internal component to form a fold.

7. Claims 31, 34, 37-40, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Akerfeldt et al. (6,508,828). Akerfeldt et al. disclose, in figures 1 and 6-18, a tissue puncture closure device and a method of sealing an internal tissue puncture having a carrier tube (24) or insertion sheath, an anchor (2), a sealing plug (6) that is folded at least once or from a V-shape (fig. 18) into a substantially straight shape, and a filament (18).

Allowable Subject Matter

8. Claims 21, 23, 24, 26, 27, 29, 30, 32, and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 5-14, 35, and 36 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination discloses a tissue puncture closure device having, inter alia, a filament, an anchor, and a sealing plug or first external component, and a second external component folded and engaged with the first external component, where the sealing plug comprises an X-shape in cross-section or two components folded into a generally U-shape and interconnected with

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each other, where the external component is collagen sponge folded into legs of a general V-shaped folded along a centerline; where the filament alternately extends through holes in two cross members of the sealing plug in a spiral pattern, where first and second halves of a flexible sealing plug are folded latitudinally adjacent to one another, and where the sealing plug is folded from an original V-shape to a rectangular shape.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Response to Amendment

11. Applicant's arguments filed on February 16, 2006 have been fully considered but they are not persuasive: See the restated and new grounds of rejection above.

With respect to arguments regarding the rejection under 35 U.S.C. 112: The "open rectangle" has not been defined *within the claim*, although clarification was made in the arguments and the text of specification. The claims should set forth the conditions for establishment of an "open rectangle" as compared to, for example, a closed rectangle or a folded structure.

With respect to arguments regarding the rejection based upon the Rousseau referenced: The Examiner agrees with the Applicant that "the same element cannot comprise both an anchor and a sealing plug." The Examiner had relied upon Figure 1 of Rousseau, which apparently mistakenly labeled the first and second conical members as "12" and "14," respectively, instead of "14" for both, separate elements.

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The rejection above clarifies the Examiner's interpretation of an anchor and a sealing plug each having "14" as its element number. Also, The Examiner has pointed out that the sealing plug does indeed have two cross members having a weave pattern. That is, the "mesh," as disclosed by Rousseau, constitutes at least two filamentous members that are crossed or woven to form the mesh.

With respect to arguments regarding the Nash reference (5,312,435): See the rejection above. Also, stiffness is a relative term. The anchor (32) of Nash is a relatively stiff member as compared to the sealing member and to the filament.

With respect to the Akerfeldt reference: The argument are directed to the intended use of the invention rather than to structural differences between the invention and the reference device. Structurally, the invention and the reference device are the same. That is, the "introducer" of Akerfeldt is structurally the same as the carrier tube of the invention.

The courts have held that a new use for an old device must be claimed in the form of a method claim, see *In re Zierdon* (CCPA 1969). See also *In re Casey*, 152 USPQ 235 (CCPA 1967) and in *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since the invention in the present case is structurally the same as the reference devices, the PTO cannot issue an apparatus claim to an already known device.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-

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4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

April 25, 2006